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## **Terry Goddard Announces \$60 Million Settlement with Pfizer**

(Phoenix, Ariz. – October 22, 2008) Attorney General Terry Goddard announced a \$60 million settlement today with Pfizer Inc. (Pfizer). The settlement resolves a lengthy investigation by Attorneys General from 32 states and the District of Columbia into the company's promotion of the drugs Celebrex® and Bextra®.

Arizona's share of the \$60 million payment is \$2,500,656. The settlement takes the form of a consent judgment and does not constitute an admission of wrongdoing.

"This judgment sends a strong message to the pharmaceutical industry: We will not tolerate deceptive or misleading drug promotion," Goddard said.

The states initiated the investigation to determine whether Pfizer misrepresented its non-steroidal anti-inflammatory (NSAIDS) drugs Celebrex and Bextra as safer and more effective than traditional NSAIDS. Traditional NSAIDS, such as Ibuprofen (Advil®) and naproxen (Aleve®), are used to treat pain and inflammation. However, they also have the potential to cause serious gastro-intestinal (GI) side effects.

The states alleged that, contrary to Pfizer's claims, neither Celebrex nor Bextra were more effective than traditional NSAIDS at relieving pain or reducing serious GI side effects. Furthermore, the drugs allegedly increased the risk of serious cardiovascular problems, such as heart attacks and strokes.

According to the complaint, Pfizer also engaged in an aggressive, deceptive and unlawful campaign to promote Bextra for "off-label" uses that were unapproved by the U.S. Food and Drug Administration (FDA), including treatment of acute and post-surgical pain.

Pfizer's "off-label" promotional campaign allegedly included:

- Distributing hundreds of thousands of copies of a positive study from the denied FDA
  application, as well as other positive studies relating to use of high-dose Bextra, without
  distributing or disclosing the negative study that was the basis for FDA's rejection or
  disclosing that FDA had not approved Bextra for acute and surgical pain.
- Attempting to influence prominent doctors with paid consultancies.
- Distributing hundreds of thousands of samples of high-dose Bextra to surgeons and other specialists whose only possible use for the drug was for acute and surgical pain.

- Providing bonuses and trips to encourage sales representatives to promote Bextra for acute and surgical pain.
- Using Continuing Medical Education to promote Bextra for acute and surgical pain.
- Misrepresenting Bextra's safety.

According to the terms of the settlement, Pfizer agrees to abstain from the following practices:

- Deceptive use of scientific data when marketing to doctors.
- "Ghost writing" of articles and studies.
- Failing to adequately disclose conflicts of interest for Pfizer promotional speakers when these consultants also speak at supposedly independent Continuing Medical Education courses.
- Distributing samples with the intent to encourage off-label prescribing.
- Distributing information about an off-label use without disclosing that the FDA rejected the use or the basis for the rejection.
- Providing incentives to sales staff to increase off-label prescribing.
- Providing financial incentives to physicians for time spent with Pfizer sales reps.
- Using medical grants to encourage doctors' and hospitals' use of Pfizer products.

The settlement also requires Pfizer to submit all "direct-to-consumer" television drug advertisements to the FDA for approval and to comply with any FDA revisions before running the advertisement.

The settlement also requires Pfizer to register all clinical trials and post clinical trial results and to ensure that Pfizer provides subjects in clinical trials adequate informed consent.

Joining Arizona in today's settlement are: Alaska, Arkansas, California, Connecticut, Florida, District of Columbia, Idaho, Illinois, Iowa, Kansas, Maine, Maryland, Massachusetts, Michigan, Montana, Nebraska, Nevada, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oregon, Pennsylvania, South Carolina, South Dakota, Tennessee, Texas, Vermont, Virginia, Washington and Wisconsin.

Assistant Attorney General Noreen R. Matts handled this matter and served as a co-chair of the multi-state negotiating team. For additional information, contact Anne Hilby at (602) 542-8019.